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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,982

05/02/2006

Makoto Koizumi

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EXAMINER

STAPLES, MARK

ART UNIT

PAPER NUMBER

1637

MAIL DATE

DELIVERY MODE

08/20/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,982	<b>Applicant(s)</b> KOIZUMI, MAKOTO	
	<b>Examiner</b> Mark Staples	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-54 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 44-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12-43 and 52-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 April 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/23/08, 08/03/06, 06/23/06, &amp; 05/02/06</u> .            | 6) <input type="checkbox"/> Other: _____                          |



### **DETAILED ACTION**

1. Applicant's amendment of claims 1-4 and 12-17 in the paper filed on 04/23/2008 is acknowledged.

Claims 1-5, 12-43, and 52-54 are pending and at issue.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### **Objections and Rejections that are Withdrawn**

2. The objection to the title is withdrawn in light of Applicant's amendment of the title.

3. The objection to the improper indication of the trademark CHROMOLITH® is withdrawn in light of Applicant's amendment to properly indicate this trademark.

#### ***Replacement Drawing Accepted***

4. The replacement drawing of Figure 1 filed on 04/23/2008 is accepted.

#### ***Priority***

5. Receipt is acknowledged of the certified English translations of the 2003-378039 filed in Japan and 2004-121080 application filed in Japan and submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Information Disclosure Statements, IDS***

6. The IDS filed on 04/23/2008 has been considered. The appropriate parts of IDS filed on 05/02/2006 and 08/03/2006 as correctly noted by Applicant have been considered.

7. Examiner has found the English language Int. Search Report for PCT/JP2004/016715 and it has been considered on the IDS filed on 06/23/2006. The Reasoned Statement filed on 06/23/2006 is not however in English and has not been considered.

***Sequence Rules Compliance***

8. It is acknowledged that Applicant has amended the specification to be in compliance with sequence rules.

***Claim Rejections Withdrawn - 35 USC § 112 Second Paragraph***

9. The rejections of claims 1-5, 12-43, and 52-54 in sections 9-16 of the previous Office Action mailed on 02/19/2008 under 35 USC § 112 Second Paragraph are withdrawn in light of Applicant's amendments to overcome these rejections.

10. The rejections of claims 12-17, 20, 23-25, 29-32, 36-38, 41-43, and 52-54 in sections 17-21 of the previous Office Action mailed on 02/19/2008 under 35 USC § 112 Second Paragraph are withdrawn. Applicant's arguments are persuasive.

***Rejections that are Maintained***

***Claim Rejections Maintained - 35 USC § 103***

11. The rejection of claims 1-5, 23, 29, and 41 under 35 U.S.C. 103(a) as being unpatentable over Latorra et al. (06/04/2003) and Koizumi et al. (2003) is maintained. Applicant's arguments filed 04/23/2008 have been fully considered but they are not persuasive.

Applicant argues that Latorra et al. do not teach or suggest an LNA nor an ENA unit which is the third nucleotide from the 3' end of the oligonucleotide. Applicant argues that Latorra et al. only teach an LNA primer at the 3' end. This is not the case however, as Latorra et al. teach:

“A total of 16 forward DNA and 3' LNA primers were designed for each of three pUC19 targets, and included match and the three other possible mismatch combinations at the last four positions of each 3' end” (see legend to Table 1).

Applicant argues that the above sentence means that an LNA was only placed at the 3' end, that is, at the last position of the 3' end. However, Latorra et al. clearly teach the LNA is placed “at the last four positions of each 3' end”. Furthermore, this is done for each of the three forward primers in sets 1-3 as given in the Table 1. The last four positions of each of these primers include the third position from their 3' end. Each of these three forward primers has a four base 3' end in which the four bases are T, C, G, and A in different orders. Primers were then made where each of these bases was substituted with an LNA complementary match to corresponding template base and with each of the remaining three LNA mismatches (non-complementary bases, see Figure 2 and its legend). Thus Latorra et al. not only designed 16 such LNA primers for each of the three forward primers but made these primers as evidenced by Figure 2.

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Thus as Lattora et al. teach an LNA unit which is the third nucleotide from the 3' end. As given in the previous Office action, Koizumi et al. teach ENA units and teach that ENA units can be substituted for LNA units. Thus, as also given previously, it would have been obvious to substitute the ENA units of Koizumi et al. for the LNA units of Lattora et al. to arrive at the claimed invention.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus the rejection is maintained.

12. The rejection of claims 12-19 and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lattora et al., Koizumi et al. , and Weston et al. (2002) is maintained. Applicant's arguments filed 04/23/2008 have been fully considered but they are not persuasive.

Applicant argues that as the rejection over Lattora et al. and Koizumi et al. should not be maintained that the rejection in view of Weston et al. should be withdrawn. However as the rejection over Lattora et al. and Koizumi et al. is maintained.

In further response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the

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rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus the rejection is maintained.

13. The rejection of claims 20-22, 24-28, 30-40, and 42-43 under 35 U.S.C. 103(a) as being unpatentable over Latorra et al. and Koizumi et al., and further in view of Stanton et al. (2001) is maintained. Applicant's arguments filed 04/23/2008 have been fully considered but they are not persuasive.

Applicant argues that as the rejection over Latorra et al. and Koizumi et al. should not be maintained that the rejection in view of Stanton et al. should be withdrawn. However as the rejection over Latorra et al. and Koizumi et al. is maintained.

In further response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus the rejection is maintained



**Conclusion**

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Thursday, 9:00 a.m. to 6:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Staples

/M. S./

Examiner, Art Unit 1637

August 14, 2008

/Kenneth R Horlick/

Primary Examiner, Art Unit 1637